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December 8, 2010

Linda G. Greenberg

Department of Health and Human Services

Office of Consumer Information and Insurance Oversight

Room 445-G

Hubert H. Humphrey Building 200 Independence Avenue, SW

Washington, DC 20201

Attention: OCIIO-9986-NC

Dear Ms. Greenberg:

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, appreciates this opportunity to submit comments regarding the federal external review process in instances where there is no applicable State process for external review of health plan denials, as required under the Affordable Care Act.

In general, the Academy would urge that the Departments of Health and Human Services and Labor request that Independent Review Organizations (IROs) conducting federal external review of health plan denials for children consult with pediatric primary care and subspecialty experts; that the child's medical home be informed of the result of such external review by the IRO with the consent of the family; and that all of the consumer protections from the National Association of Insurance Commissioners Model Act be included in the federal external review process.

Thank you very much for your attention to the views of the American Academy of Pediatrics.

Sincerely,

O. Marion Burton, MD, FAAP

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President

OMB:rh

Federal External Review Process

(11) Are there any special considerations HHS and/or DOL should be aware of in considering a specialized contract for urgent care appeals or for experimental and investigational treatments? Would such an approach have an impact on coordination?

Yes, there are special considerations the American Academy of Pediatrics (the Academy) wishes to highlight. First, large-scale clinical trials, and in turn evidence-based medicine, are not as extensive in pediatrics as in adult medicine; therefore, in considering specialized contracts for urgent care appeals and for experimental and investigational treatments, HHS and/or DOL should ensure that contracted IROs are equipped with appropriate knowledge of pediatric medical necessity model contract knowledge and include pediatric-specific medical expertise. Bright Futures guidelines (which are referred to in section 2713 of the Affordable Care Act as the appropriate preventive services package for no copay coverage in non-grandfathered health plans) state: "For many interventions that are commonly performed in child or adolescent care, no, or few, properly constructed studies have been done that link the intervention with intended health outcomes. Absent evidence does not demonstrate a lack of usefulness, however. The lack of evidence of effectiveness most often simply reflects the lack of study." While the National Association of Insurance Commissioner's Uniform Health Carrier External Review Model Act (the Model Act) Section 8(H)(3) requires that appropriate health care professionals be consulted for external review, it is unclear whether pediatric expertise must be included. External reviewer criteria include having a scope of practice encompassing the service or treatment in question and having experience in managing patients with the condition under review. Though seemingly obvious, it is critical to appreciate the fact that children are not simply small adults. The standard of care for pediatric medicine can often differ significantly from that of adult medicine. For example, having treated an adult with diabetes, seizure disorder, or depression is markedly different from having treated a child with the same diagnosis.

Moreover, fewer studies have been conducted in children, and thus pediatricians and other child health professionals have fewer drugs in their armamentarium known to be clinically effective. Thus, many drugs are prescribed for off-label use by pediatricians. Pediatric clinical interventions are less frequently tested in double-blinded, randomized controlled trials, though providers' clinical judgment deems them appropriate, and necessary. External reviews must adequately reflect the reality that children and adolescents require special consideration. We strongly recommend that Board certified pediatric primary care and subspecialty pediatricians be included in any external review process conducted by an IRO authorized by the federal government.

Second, we urge the Departments to contemplate the value to families of informing a child's medical home of any federal external review benefit determination – whether adverse or not – if the child's family has given consent to do so. Providers advocate for their patients and often interact with insurance plans more frequently than do patients' families. Thus, informing the child's medical home of insurance decisions may improve advocacy efforts on behalf of pediatric patients and streamline their treatment.

Third, we advise that all consumer protections from the NAIC Model Act be applied to federal external review laws. We see no reason that some children should benefit from some structures and not from others. In particular, requiring that insurers produce reports on the frequency and type of external reviews (as required by Sec. 15(B)) could be an important component of plan quality. Older children and their families and guardians may want to access this information through healthcare.gov, for instance. Posting this information on-line would allow families to make better-informed decisions about which insurance plans best fit their needs. Finally, we would also suggest that the IROs engage in good quality improvement practices as well. IROs should be required to develop an action plan for areas that are identified to not be working as well as planned and how these will be addressed with the IRO structure.

Additionally, it may be appropriate to request that IROs submit their reports to HHS as well as to State Insurance Commissioners. By providing these materials to HHS, the Secretary, with the Office of Consumer Information and Insurance Oversight, would have the necessary data to reflect appropriate information for consumer use.

Thank you for the opportunity to comment. If you have any questions, please contact Robert Hall with the American Academy of Pediatrics at 202/724-3301 or RHall@aap.org.